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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/032,659

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/032,659	<b>Applicant(s)</b> KRAMER ET AL.	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,14-16,22-24,26-29 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 14-16, 22-24, 26-29, and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1, 9, 14-16, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (5,954,724). Davidson discloses the invention substantially as claimed. Davidson discloses, at least in figures 1A and 1B and in col. 8, lines 21-25; col. 11, line 33 to col. 12, line 40; a medical device or stent (10) including a metal alloy substrate having a fine grain size, where the substrate is a titanium based alloy, and where the stent is configured with a plurality of struts or elongate elements. However, Davidson does not disclose that the average grain size is in the range of one to ten microns, that the number of grains across a strut thickness is in the range of five to fifteen, and that the number of grains across an element thickness is more than six. Nevertheless, Davidson discloses that the alloy substrate can be mechanically worked

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“to optimize grain size” (and inherently, grain number, since the grain size affects the number of grains within a given device configuration). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size or number the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of grain size and/or number) involves only routine skill in the art.

3. Claims 3-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (5,954,724) or Davidson '724 in view of Davidson (5,415,704) or Davidson '704. Davidson '724 discloses the invention substantially as claimed.

Davidson '724 discloses medical devices comprising titanium-based alloy substrates with fine grain size. However, Davidson '724 does not disclose a substrate comprising 316L stainless steel, cobalt-chromium alloy, or a tantalum-based alloy. Davidson '704 teaches, at least in col. 3, line 63 to col. 4, line 62; col. 5, lines 9-51; and col. 6, line 68 to col. 7, line 33; other metal alloy substrates, besides titanium-based alloys, usable for medical devices, where the substrates include 316L stainless steel, cobalt-chromium alloy, tantalum-based alloys, and where the substrates possess fine grain. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Davidson '704, to include the metal alloy substrates as claimed for the medical devices as claimed in Davidson '724. Such materials are readily hardened and strengthened by oxidation and nitridation processes, and would be desirable for medical devices subject to load-bearing and abrasion.

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4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lam (5,569,295) in view of Simpson et al. (4,770,725). Lam discloses the invention substantially as claimed. Lam discloses, at least in col. 7, lines 8-37; a medical device comprising a metal alloy substrate that is a nickel-titanium alloy. However, Lam does not disclose that the substrate has an average grain size in the range of one to ten microns. Simpson et al. teach, at least in col. 10, lines 13-33; a nickel-titanium alloy with fine grain size. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Simpson et al., to form the device of Lam from a nickel-titanium alloy substrate with fine grain size. Such a substrate would produce a device with shape memory, excellent formability, and excellent machinability. Simpson et al., however, also do not disclose that the average grain size of the substrate is in the range of one to ten microns. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of grain size) involves only routine skill in the art.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (4,830,003) in view of Braun et al. (6,129,997). Wolff et al. disclose the invention substantially as claimed. Wolff et al. disclose, at least in col. 3, lines 35-39 and col. 4, lines 8-11; a medical device comprising a metal substrate that includes platinum-iridium. However, Wolff et al. do not disclose that the substrate is a platinum-iridium alloy with an average grain size in the range of one to ten microns. Braun et al. teach, at least in

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col. 1, line 49 to col. 2, line 14 and col. 4, lines 19-24; a platinum-iridium alloy with fine grain size. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Braun et al., to form the device of Wolff et al. from a platinum-iridium alloy substrate with fine grain size. Such a substrate would produce a device with improved strength and improved welds between wires. Braun et al., however, also do not disclose that the average grain size of the substrate is in the range of one to ten microns. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of grain size) involves only routine skill in the art.

6. Claims 22 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Davidson (5,954,724). Frantzen discloses the invention substantially as claimed. Frantzen discloses, at least in figures 1 and 5 and in col. 8, lines 30-63; an intravascular stent comprising a metal alloy substrate. Frantzen discloses that the stent includes a plurality of interconnected cylindrical rings or a plurality of struts or elongate elements (e.g. 20 or 120) and straight links (e.g., 50 or 150) or undulating links (e.g., 180). However, Frantzen does not disclose that the substrate has an average grain size in the range of one to ten microns or about five microns. Davidson teaches, at least in figures 1A and 1B and in col. 8, lines 21-25; col. 11, line 33 to col. 12, line 40; a stent (10) including a metal alloy substrate having a fine grain size. However, Davidson also does not disclose that the average grain size is in

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the range of one to ten microns or about five microns. Nevertheless, Davidson discloses that the alloy substrate can be mechanically worked "to optimize grain size." Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size or number the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of grain size) involves only routine skill in the art.

7. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Davidson (5,954,724) or Davidson '724, and further in view of Davidson (5,415,704) or Davidson '704. Frantzen in view of Davidson '724 discloses the invention substantially as claimed. Frantzen view of Davidson '724 discloses medical devices comprising metal alloy substrates with fine grain size. However, the combination does not disclose a substrate comprising 316L stainless steel. Davidson '704 teaches, at least in col. 3, line 63 to col. 4, line 62; col. 5, lines 9-51; and col. 6, line 68 to col. 7, line 33; other metal alloy substrates, besides titanium-based alloys, usable for medical devices, where the substrates include 316L stainless steel, and where the substrates possess fine grain. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Davidson '704, to include 316L stainless steel in the stent of Frantzen in view of Davidson '724. Such a biocompatible material is readily hardened and strengthened by oxidation and nitridation processes, and would be desirable for a medical device subject to load-bearing or abrasion.

***Response to Amendment***

8. Applicant's arguments with respect to claims 1, 3-10, 14-16, 22-24, 26-29, and 41-45 have been considered but are not persuasive. With respect to arguments regarding the rejection of claims based on the teachings of Davidson (5,954,724), Simpson et al., and Braun et al: The Applicant posits that the Examiner's conclusion of obviousness (regarding the finding of optimum, fine grain size for a metal alloy substrate in a medical device) is based upon improper hindsight reasoning. The Examiner disagrees, since it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. Davidson, for example, particularly teaches knowledge within the level of ordinary skill; i.e., that grain size, as well as strength, elastic modulus and toughness, for a metal alloy can be optimized according to desired values for various medical devices. Davidson does not specifically suggest an optimal grain size, because one of ordinary skill would know that grain size inherently affects the mechanical properties of a material; e.g., strength and toughness; and that grain size and the mechanical properties of a material can be intentionally varied. Thus, Davidson teaches the general conditions of the claims, such that discovering an optimal or workable range of grain size involves only routine skill in the art, where the range may obviously include one to ten microns, as claimed, for



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application to a particular medical device. Also obviously, one of ordinary skill would optimize grain size and a material's mechanical properties, so that a medical device would not unduly fail under mechanical stress or known load conditions that could cause "cracks and/or heavy slip band formation."

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

August 9, 2008